



10534257 - GAU: 1644

PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|------------------------------|---|----|---|------------------------|------------------------|
| Substitute for form 1449/PTO | | | | Complete if Known | |
| | | | | Application Number | 10/534,257-Conf. #4508 |
| | | | | Filing Date | May 10, 2005 |
| | | | | First Named Inventor | Shoji FURUSAKO |
| | | | | Art Unit | 1644 |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | 1110-0326PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| AA* | US-2004/0141917-A1 | | 07-22-2004 | Achen et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | T ⁶ |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|-----------------------|---|--|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ² |
| | | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

Birch, Stewart, Kolasch & Birch, LLP

MAA/bsh

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.W./

Used In Lieu of PTO/SB/08A/B
(Based on PTO 04-07 version)

| | | | | | |
|--|---|----|---|------------------------|------------------------|
| Substitute for form 1449/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/534,257-Conf. #4508 |
| (Use as many sheets as necessary) | | | | Filing Date | May 10, 2005 |
| | | | | First Named Inventor | Shoji FURUSAKO |
| | | | | Art Unit | 1645 |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | 1110-0326PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|--|------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | MM-DD-YYYY | | |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|---|------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | MM-DD-YYYY | | |
| | | | | | |

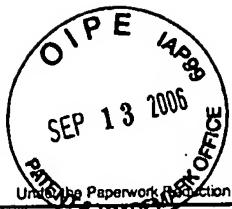
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional) ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3) ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached

| NON PATENT LITERATURE DOCUMENTS | | | | | | |
|---------------------------------|---|---|--|--|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | | |
| | | | | | | T ² |
| | | | | | | |
| CA** | MANOCHA, Sanjay et al.; Expert Opin. Investig. Drugs, Vol. 11, No. 12, pp. 1795-1812 (2002) | | | | | ✓ |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹CITE NO : Those document(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120

¹Applicant's unique citation designation number (optional) ²Applicant is to place a check mark here if English language Translation is attached

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|



PTO/SB/08a/b (07-06)

Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|------------------------|------------------|
| Substitute for form 1449A/B/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Application Number | 10/534,257 |
| Sheet | 1 | of | 1 | Filing Date | May 10, 2005 |
| | | | | First Named Inventor | Shoji FURUSAKO |
| | | | | Art Unit | 1645 |
| | | | | Examiner Name | Not Yet Assigned |
| | | | | Attorney Docket Number | 1110-0326PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| AA* | US-5,766,593-A | 06-16-1998 | Lichenstein et al. | | |
| AB* | US-6,916,628-B1 | 07-12-2005 | Furusako et al. | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number-Kind Code ⁴ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | T ⁵ |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(e)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|---|--|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | |
| CA | Lederman et al., Molecular Immunology, Vol. 28, pp. 1171-1181, (1991). | | | | T ² |
| CB | Li et al., Biochemistry: Proc. Natl. Acad. Sci. USA, Vol. 77, No. 6, pp. 3211-3214, (June 1980). | | | | |
| CC | Abaza et al., Journal of Protein Chemistry, Vol. 11, No. 5, pp. 433-444, (1992). | | | | |
| CD | Coleman et al., Research in Immunology, Vol. 145, No. 1, pp. 33-36, (1994). | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

Birch, Stewart, Kolasch & Birch, LLP

MAA/srm

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.W./



PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|------------------------|------------------------|
| Substitute for form 1449A/B/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/534,257-Conf. #4508 |
| (Use as many sheets as necessary) | | | | Filing Date | May 10, 2005 |
| Sheet | 1 | of | 1 | First Named Inventor | Shoji FURUSAKO |
| | | | | Art'Unit | 1645 |
| | | | | Examiner Name | Not Yet Assigned |
| | | | | Attorney Docket Number | 1110-0326PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | T ⁶ |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|-----------------------|---|--|--|--|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | |
| | CA | Endo et al., The Japanese Association for Infectious Diseases, 52nd East Japan Meeting held 10/31/2003 (English translation) | | | |
| | CB | Endo et al., The Journal of Japanese Association for Acute Medicine, Vol. 14, No. 10, p. 602 (October 2003), English translation. | | | |
| | CC | The Official Journal of the Shock Society, Abstract of the 6th World Congress on Trauma, Shock, Inflammation and Sepsis (March 2004) | | | |
| | CD | Endo et al., Journal of the Japanese Society of Intensive Care Medicine, Vol. 11, Supplement, p. 244, January 2004, English translation | | | |
| | CE | The Official Journal of the Critical Care Forum, Vol. 8, Supplement 1, pp. S94-S94 (March 2004) | | | |
| | CF | Abstract of the 104th General Assembly of the Japan Surgical Society, April 2004, English translation. | | | |
| | CG | Official Journal of the European Society of Intensive Care Medicine and the European Society of Paediatric & Neonatal Intensive Care, Vol. 30, Supplement 1, p. S192, September 2004 | | | |
| | CH | Endo et al., Program and Abstracts of the 10th Conference of the Japan Endotoxin Society, November 15, 2004, English translation. | | | |
| | CI | Journal of Endotoxin Research, Vol. 10, No. 5, p. 373, November 2004. | | | |
| | CJ | Endo et al., Journal of the Japanese Society of Intensive Care Medicine, Vol. 12, Supplement, p. 121, January 2005, English translation. | | | |
| | CK | Endo et al., The Journal of the Japanese Association for Infectious Diseases, Vol. 80, Supplement, p. 271, March 2006, English translation. | | | |
| | CL | Endo et al., Japan Journal of Critical Care for Endotoxemia, Vol. 9, No. 1, pp. 46-50, 2005 (English Abstract on page 50). | | | |
| | CM | Yaegashi et al., Japanese Society of Chemotherapy; pp. 234-238, No. 11 (2005). | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

| | | | |
|--------------------------------------|--|-----------------|-----------|
| Examiner Signature | | Date Considered | 2/11/2008 |
| Birch, Stewart, Kolasch & Birch, LLP | | MAA: bmp | |

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.W./



10534257 - GAU: 1644

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|--------------------------|------------------------|
| Substitute for form 1449A/B/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Application Number | 10/534,257-Conf. #4508 |
| Sheet | 1 | of | 1 | Filing Date | May 10, 2005 |
| | | | | First Named Inventor | Shoji FURUSAKO |
| | | | | Art Unit | 4645- |
| | | | | Examiner Name | Not Yet Assigned |
| | | | | Attorney Docket Number | 1110-0326PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|------------------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|---------------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | BA | DD- 286876 A5 | 10-27-1983 | Ernst-Moritz-Arndt-Universität Greifswald | A |
| | | | | | |
| | | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|--|--|---|--|--|--|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | |
| CA | LANDMANN, Regine et al.; <i>The Journal of Infectious Disease</i> , Vol. 171, pp. 639-644 (1995) | | | | |
| CB | STELTER, Felix et al.; <i>European Journal of Biochemistry</i> (Germany); Vol. 236, pp. 457-464 (1996) | | | | |
| CC | BAZIL, Vladimir et al.; <i>European Journal of Immunology</i> (Germany); Vol. 16, pp. 1583-1589 (1986) | | | | |
| CD | SCHÜTT, Christine et al.; <i>Allergie und Immunologie</i> (Germany), Vol. 34, pp. 17-26 (1988) | | | | |
| CE | VAN VOORHIS, Wesley C. et al.; <i>Journal of Experimental Medicine</i> (USA), Vol. 158, pp. 126-145 (1983) | | | | |
| CF | BAZIL, Vladimir et al.; <i>Molecular Immunology</i> (UK), Vol. 26, pp. 657-662 (1989) | | | | |
| CG | GRUNWALD, U. et al.; <i>Journal of Immunological Methods</i> (Holland); Vol. 155, pp. 225-232 (1992) | | | | |
| CH | BURGMANN, Heinz et al.; <i>Clinical Immunology and Immunopathology</i> (USA), Vol. 80, pp. 307-310 (1996) | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

"A" equals Abstract.

| | | | |
|--------------------|--|-----------------|-----------|
| Examiner Signature | | Date Considered | 2/11/2008 |
|--------------------|--|-----------------|-----------|

Birch, Stewart, Kolasch & Birch, LLP

MAA/bmp

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.W./



10534257 - GAU: 1644

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|------------------------|------------------------|
| Substitute for form 1449A/B/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Application Number | 10/534,257-Conf. #4508 |
| Sheet | 1 | of | 1 | Filing Date | May 10, 2005 |
| | | | | First Named Inventor | Shoji FURUSAKO |
| | | | | Art Unit | 4645 |
| | | | | Examiner Name | Not Yet Assigned |
| | | | | Attorney Docket Number | 1110-0326PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|------------------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|---------------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | T ⁶ |
| BA | | EP 1 275 713 A1 | 01-15-2003 | | |
| BB | | EP 1 336 620 A1 | 08-20-2003 | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|--|-----------------------|---|--|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (In CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ² |
| | | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

| | | | |
|--------------------|--|-----------------|-----------|
| Examiner Signature | | Date Considered | 2/11/2008 |
|--------------------|--|-----------------|-----------|

Birch, Stewart, Kolasch & Birch, LLP

MAA/bmp

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.W./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---------------------------------|---|----|---|------------------------|------------------|
| Substitute for form 1449A/B/PTO | | | | Complete if Known | |
| | | | | Application Number | Not Yet Assigned |
| | | | | Filing Date | May 10, 2005 |
| | | | | First Named Inventor | Shoji FURUSAKO |
| | | | | Art Unit | N/A |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 1 | of | 1 | Attorney Docket Number | 1110-0326PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| BA** | | WO-96/20956-A1 | 07-11-1996 | | |
| BB** | | EP-1213586-A1 | 06-12-2002 | | |
| BC** | | WO-01/72993-A1 | 10-04-2001 | | |
| BD** | | WO-02/42333-A1 | 05-30-2002 | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ** CITE NO.: Those document(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|-----------------------|---|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | T ² |
| CA** | | Shigeatsu ENDO et al., Journal of Japanese Association for Acute Medicine, 15 October, 2003, Vol. 14, No. 10, pages 602, Op-285 | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ** CITE NO.: Those document(s) which are marked with an double asterisk (**) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

| | | | |
|--------------------------------------|---|-----------------|-----------|
| Examiner Signature |  | Date Considered | 2/11/2008 |
| Birch, Stewart, Kolasch & Birch, LLP | | MAA/sml | |

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.W./



| | | | | | |
|--|---|----|---|------------------------|------------------------|
| Substitute for form 1449/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/534,257-Conf. #4508 |
| (Use as many sheets as necessary) | | | | Filing Date | May 10, 2005 |
| Sheet | 1 | of | 1 | First Named Inventor | Shoji FURUSAKO |
| | | | | Art Unit | 1644 |
| | | | | Examiner Name | Growder, C. Sharon Wen |
| | | | | Attorney Docket Number | 1110-0326PUS1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear |
| | | | | | <input checked="" type="checkbox"/> |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.18 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|-----------------------|---|--|--|-------------------------------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | <input checked="" type="checkbox"/> |
| | CA | Yaegashi et al., Japanese Society of Chemotherapy and The Japanese Association for the Infections Diseases, Vol. 11, No. 5, (2005), pps 234-238 | | | |
| | CB | Bufier et al., European Journal of Immunology, February 1995, Vol. 25, No. 2, XP-002458844, pps 604-610 | | | |
| | CC | Majerle et al., European Journal of Physiology 2000, Vol. 439, No. 3, XP-002458846 pps R109-R110 | | | |
| | CD | Stelter et al., European Journal of Biochemistry, Vol. 243, No. 1-2, (1997), XP-002458847, pps 100-109 | | | |
| | CE | Majerle et al., Protein Expression and Purification, Vol. 17, No. 1, 1999, pps 96-104 | | | |
| | CF | Iwaki et al. Biochemical and Biophysical Research Communications, Vol. 328, No. 1, (2005), pps 173-176 | | | |

| | | | |
|--------------------|--|-----------------|-----------|
| Examiner Signature | | Date Considered | 2/11/2008 |
|--------------------|--|-----------------|-----------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.